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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/930,503	08/16/2001	James L. Henry	39245-173913	1568

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EXAMINER	
ASHEN, JON BENJAMIN	
ART UNIT	**PAPER NUMBER**
1635	

DATE MAILED: 06/10/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/930,503	HENRY ET AL.	
	Examiner	Art Unit	
	Jon B. Ashen	1635	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 1-137 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) 1-137 are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 2-4, 6-21, 36-38, 40-42, 44-56, 71-90, 106 and 109-125 are drawn to methods of treating a pathological condition by administration of an sense or antisense oligonucleotide or oligonucleotide analog, classified in class 514, subclass 44.

II. Claims 2, 3, 6-21, 36-38, 40-42, 44-56, 71-90, 106, 109-111 and 113-125 are drawn to methods of treating a pathological condition by administering an oligonucleotide suitable to bind proteins involved in said condition; e.g., aptamers, classified in class 536, subclass 24.1.

III. Claims 36-37, 42-58, 71-72, 79-93,106-111 and 113-125 are drawn to a method of treating a pathological condition by administering a non-nucleotide disruptor compound, classified in class 514, subclass 2.

IV. Claims 23-24, 26-33, 60-63, 65-68, 96-103, 127-133, 136-137 are drawn to pharmaceutical preparations comprising oligonucleotides or oligonucleotide analogs and kits comprising said pharmaceutical preparations, classified in class 514, subclass 44.

V. Claims 60-61, 64, 65-68, 96, 101-104, 127-133 and 135-137 are drawn to pharmaceutical preparations comprising non-nucleotide disruptor

compounds and kits comprising said pharmaceutical preparations, classified in class 514, subclass 2.

2. Applicant is advised that claims 95-99 recite, "the pharmaceutical preparation of claim 78." Applicant is advised that there is no claim for "a pharmaceutical preparation" in claim 78 (or in any of the claims from which claim 78 depends). This is an apparent typographical error. This examiner assumes that applicant intended to use "94" in place of "78" in all places where "78" is recited in claims 95-99.

3. Claims 1, 35 and 70 link(s) inventions of groups I-III. The restriction requirement among the linked inventions is subject to the nonallowance of the linking claim(s), 1, 35 and 70. Claims 34, 69 and 105 link(s) inventions of groups I-V. The restriction requirement among the linked inventions is subject to the nonallowance of the linking claim(s), 34, 69 and 105. Claims 59, 94, 126 and 134 link(s) inventions of groups VI and V. The restriction requirement among the linked inventions is subject to the nonallowance of the linking claim(s), claims, 59, 94, 126 and 134. Claims 5, 39 and 74 link(s) inventions of claims 7-8, 41 and 76 (which are in group I). The restriction requirement among the linked inventions is subject to the nonallowance of the linking claim(s), claim 5, 39 and 74. Claims 5, 39 and 74 link(s) inventions of claims 7-8, 41 and 76 (which are in group II). The restriction requirement among the linked inventions is subject to the nonallowance of the linking claim(s), claim 5, 39 and 74. Claims 22, 25, 62, and 98 link(s) inventions of claims 24, 63, 97 and 99 (which are in group IV). The

restriction requirement among the linked inventions is subject to the nonallowance of the linking claim(s), claims 22, 25, 62, and 98.

4. Upon the allowance of the linking claim(s), the restriction requirement as to the linked inventions shall be withdrawn and any claim(s) depending from or otherwise including all the limitations of the allowable linking claim(s) will be entitled to examination in the instant application. Applicant(s) are advised that if any such claim(s) depending from or including all the limitations of the allowable linking claim(s) is/are presented in a continuation or divisional application, the claims of the continuation or divisional application may be subject to provisional statutory and/or nonstatutory double patenting rejections over the claims of the instant application. Where a restriction requirement is withdrawn, the provisions of 35 U.S.C. 121 are no longer applicable. *In re Ziegler*, 44 F.2d 1211, 1215, 170 USPQ 129, 131-32 (CCPA 1971). See also MPEP § 804.01.

5. Claims 2, 3, 6-21, 38, 40-41 and 73-78 are generic to groups I-II. Claims 36-37, 42, 44-56, 71-72, 79-90, 106 and 109-111 and 113-125 are generic to groups I-III. Claim 112 is generic to groups II and III. Claims 61, 65-68, 96, 101-103, 127-133 and 136-137 are generic to groups V and VI. These claims will be examined limited to the groups elected.

6. The inventions are distinct, each from the other because of the following reasons:

7. The inventions in group I and group II are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case, the invention of group I is drawn to a method of treating a pathological condition by administering a therapeutically effective amount of an oligonucleotide or oligonucleotide analog that interferes with the function or production of NK-1 receptors; e.g., antisense or gene therapy. The invention of group II is drawn to a method of treating a pathological condition by administering a therapeutically effective amount of an oligonucleotide or oligonucleotide analog, suitable to bind proteins, that interferes with the function or production of NK-1 receptors; e.g., aptamers. These inventions are not disclosed as being used together and will each have different modes of operation; the binding of an oligonucleotide to a nucleic acid encoding a gene that interferes with the function or production of NK-1 receptors; e.g., an mRNA transcript or nuclear coding region (group I), will have a different mode of operation than the binding of an oligonucleotide to a protein that interferes with the function or production of NK-1 receptors (group II); e.g., an aptamers, for example.

8. The inventions in group I and group III are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case, the invention of group I is drawn to a method of

treating a pathological condition by administering a therapeutically effective amount of an oligonucleotide or oligonucleotide analog that interferes with the function or production of NK-1 receptors; e.g., antisense or gene therapy. The invention of group III is a drawn to a method of treating a pathological condition by administering a therapeutically effective amount of a non-nucleotide disruptor compound that interferes with the function or production of NK-1 receptors. These inventions are not disclosed as being used together and will each have different modes of operation; the binding of an oligonucleotide to a nucleic acid encoding a gene that interferes with the function or production of NK-1 receptors; e.g., an mRNA transcript or nuclear coding region (group I), will have a different mode of operation than the binding of a non-nucleotide disruptor compound (group III) that interferes with the function or production of NK-1 receptors; e.g., a "mutagen" or "antibodies to nucleic acids," for example.

9. The inventions in group II and group III are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case, the invention of group II is drawn to a method of treating a pathological condition by administering a therapeutically effective amount of an oligonucleotide or oligonucleotide analog, suitable to bind proteins, that interferes with the function or production of NK-1 receptors; e.g., aptamers. The invention of group III is a drawn to a method of treating a pathological condition by administering a therapeutically effective amount of a non-nucleotide disruptor compound that interferes

with the function or production of NK-1 receptors. These inventions are not disclosed as being used together and will each have different modes of operation; the binding of an oligonucleotide to a protein that interferes with the function or production of NK-1 receptors (group II); e.g., an aptamer, will have a different mode of operation than the binding of a non-nucleotide disruptor compound; e.g., proteins that are "antibodies to nucleic acids," for example, that interferes with the function or production of NK-1 receptors (group III).

10. The inventions of groups I-II and group IV are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the invention of group IV is drawn to pharmaceutical preparations comprising an oligonucleotide or oligonucleotide analogs that interfere with the function or production of NK-1 receptors. The invention of groups I-II is drawn to methods of treating a pathological condition by administering a therapeutically effective amount of an oligonucleotide or oligonucleotide analog that interferes with the function or production of NK-1 receptors. These inventions are distinct because the product as claimed (the invention of group IV that is an oligonucleotide or oligonucleotide analog) can be used in a materially different process of using that product; i.e., a method for a hybridization assay to determine tissue or cell-specific gene expression, for example.

11. The inventions in group III and group IV are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the invention of group III is drawn to a method of treating a pathological condition by administering a therapeutically effective amount of a non-nucleotide disruptor that interferes with the function or production of NK-1 receptors. The invention of group IV is drawn to pharmaceutical compositions comprising an oligonucleotide or oligonucleotide analog that interferes with the function or production of NK-1 receptors. These inventions are not disclosed as being used together and will each have different modes of operation. The binding of a non-nucleotide disruptor compound (group III); e.g., a "mutagen" or "antibodies to nucleic acids," that interferes with the function or production of NK-1 receptors will have a different mode of operation than the binding of an oligonucleotide to a nucleic acid encoding a gene; e.g., an mRNA transcript or nuclear coding region (group IV), that interferes with the function or production of NK-1 receptors, for example.

12. The inventions in group I-II and group V are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case, the invention of groups I-II is drawn to methods of treating a pathological condition by administering a therapeutically effective amount of

an oligonucleotide or oligonucleotide analog that interferes with the function or production of NK-1 receptors. The invention of group V is drawn to pharmaceutical preparations comprising a non-nucleotide disruptor compound that interferes with the function or production of NK-1 receptors. These inventions are not disclosed as being used together and will each have different modes of operation; the binding of an oligonucleotide to a nucleic acid encoding a gene; e.g., an mRNA transcript or nuclear coding region (group I) or to a protein that interferes with the function or production of NK-1 receptors, will have a different mode of operation than he binding of a non-nucleotide disruptor compound (group V); e.g., a "mutagen" or "antibodies to nucleic acids," that interferes with the function or production of NK-1 receptors, for example.

13. Inventions of group III and V are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case, the invention of group V is drawn to pharmaceutical compositions comprising non-nucleotide disruptor compounds that interfere with the function or production of NK-1 receptors. The invention of group III is drawn to methods of treating a pathological condition by administering a therapeutically effective amount of a non-nucleotide disruptor compound that interferes with the function or production of NK-1 receptors. These inventions are distinct because the process (group III) for using the product as claimed

(group V) can be practiced with another materially different product; an oligonucleotide or oligonucleotide analog can be used in lieu of the non-nucleotide disruptor compound that is the invention of group III, for example.

14. Inventions in group IV and group V are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case, the invention of group IV is drawn to pharmaceutical compositions comprising an oligonucleotide or oligonucleotide analog that interferes with the function or production of NK-1 receptors. The invention of group V is drawn to pharmaceutical compositions comprising a non-nucleotide disruptor compound that interferes with the function or production of NK-1 receptors. These inventions are not disclosed as being used together and will each have different modes of operation; the binding of an oligonucleotide to a nucleic acid encoding a gene; e.g., an mRNA transcript or nuclear coding region (group I) or to a protein that interferes with the function or production of NK-1 receptors, will have a different mode of operation than he binding of a non-nucleotide disruptor compound (group V); e.g., a "mutagen" or "antibodies to nucleic acids," that interferes with the function or production of NK-1 receptors, for example.

15. Pursuant to 35 U.S.C. 121 and 37 C.F.R. 1.141, the nucleic acid sequences listed in claims 7, 8, 24, 41, 63, 76, 97 and 99 are subject to restriction. The

Commissioner has partially waived the requirements of 37 C.F.R. 1.141 and will permit a reasonable number of such nucleotide sequences to be claimed in a single application. Under this policy, up to 10 of independent and distinct nucleotide sequences will be examined in a single application. (see MPEP 803.04 and 2434).

16. Groups I-IV are further restricted as follows:

Claims 7, 63 and 99 specifically claim oligonucleotides or oligonucleotide analogs that are complementary to at least a portion of SEQ ID NO: 2, 4, 6 and 8. The oligonucleotide sequences of the instant inventions of claims 7, 63, and 97 are considered to be unrelated, since each oligonucleotide sequence claimed is structurally and functionally independent and distinct for the following reasons: each oligonucleotide has a unique nucleotide sequence, targets a different and specific region of a given gene or nucleic acid in a the NK-1 receptor pathway, and upon binding to a given gene or nucleic acid in the NK-1 receptor pathway, will act as either an antisense therapeutic or an agent for gene therapy (per applicants' Table (pg. 65) in the specification showing both sense and antisense oligonucleotides) to functionally modulate (increase or decrease) the expression of the given gene to varying degrees.

Claims 8, 24, 41, 76 and 97 specifically claims oligonucleotides or oligonucleotide analogs where one or more is selected from a group consisting of SEQ ID NO's: 9-59. The oligonucleotide sequences of the instant inventions of claims 8, 24, 41, 76, or 99 are considered to be unrelated, since each oligonucleotide sequence claimed is structurally and functionally independent and distinct for the following

reasons: each oligonucleotide sequence has a unique nucleotide sequence, each oligonucleotide sequence targets a different and specific region of a given gene or nucleic acid in a the NK-1 receptor pathway, and each oligonucleotide, upon binding to a given gene or nucleic acid in the NK-1 receptor pathway will act as either an antisense therapeutic or an agent for gene therapy (per applicants' Table (pg. 65) in the specification showing both sense and antisense oligonucleotides) and will functionally modulate (increase or decrease) the expression of the given gene to varying degrees.

Furthermore, a search of more than one (1) of the instant sequences presents an undue burden on the Patent and Trademark Office due to the complex nature of the search and corresponding examination of more than one (1) of the instant sequences. In view of the foregoing, one (1) nucleotide sequence is considered to be a reasonable number of sequences for examination. Accordingly, applicant is required to elect one one oligonucleotide (1) sequence from claims 7, 63 or 99; i.e., "an oligonucleotide or oligonucleotide analog complementary to at least a portion of SEQ ID NO: 2, 4, 6 and 8" and one (1) oligonucleotide sequence from claims 8, 24, 41, 76, or 99 that corresponds to the target region elected.

17. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classifications, restriction for examination purposes as indicated is proper.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

18. A telephone call was made to *** on *** to request an oral election to the above restriction requirement, but did not result in an election being made.

19. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jon B. Ashen whose telephone number is 571-272-2913. The examiner can normally be reached on Monday - Friday, 7:30 am - 4:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, John LeGuyader can be reached on 517-272-0670. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Jba

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1635